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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANTS	:	James J. BARRY, et al.
SERIAL NO.	:	09/842,833
FILING DATE	:	April 27, 2001
FOR	:	METHOD AND SYSTEM FOR DELIVERY OF COATED IMPLANTS
EXAMINER	:	Alvin J. Stewart
GROUP ART UNIT	:	3738
CUSTOMER NO.	:	23838

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PRE-APPEAL BRIEF REQUEST FOR REVIEW

SIR:

In response to the final Office Action mailed July 27, 2007, for which is response is due on or before January 28, 2007 (since January 27, 2008 falls on a Sunday) with a 3 month extension of time fee, which is hereby petitioned, Applicants request review of the Final Rejection of July 27, 2007 in the above-identified application. It is noted that the Examiner has failed to respond to the Response After Final filed October 25, 2007. A notice of appeal is being filed concurrently with this request. This review is requested for the reasons stated below.

Summary of the Claimed Subject Matter

Claim 1 is directed to a delivery system for a coated medical implant. Specifically, claim 1 recites that the implant retention region of a delivery device has an adhesion resistant treatment to prevent damage to the coating of a releasable implant when it is placed on this region. Thus, there is an adhesion resistant treatment between the surface of the implant and the surface of the delivery device.

Summary of Rejections

Claims 1, 3, 7,11 and 24-32 are rejected under 35 USC 103(a) for being allegedly rendered obvious by U.S. Patent 4,950,227 to Savin et al. ("Savin") in view of U.S. Patent 6,287,285 to Michal et al. ("Michal"). Claims 5, 6 and 8-10 are rejected under 35 USC 103(a) for being allegedly rendered obvious by Savin in view of Michal and further in view of U.S. Patent 5,902,631 to Wang et al. ("Wang").

Summary of Arguments in Response to Rejections

With regard to the first grounds of rejection, Savin fails to disclose all the limitations of claim 1. Specifically, at the least Savin does not disclose an implant adhesion-resistant treatment on the accessible surface of the delivery device; and a releasable implant having an implant coating on the surface in contact with the accessible surface, wherein the implant adhesion-resistant treatment prevents the implant coating from being stripped from an implant surface. Savin describes a stent delivery system comprising a balloon 14, a stent 16, and two sleeves 16, 18 for holding the stent on the balloon. However, Savin does not disclose an implant coating on the inner surface of the stent that is in physical communication with the balloon. The Examiner admits that "Savin et al. does not disclose a stent having a first implant coating." Although Savin states that the stent can have a lubricious coating (claim 17), there is no disclosure or teaching of what surface this coating would be on, i.e. whether the coating is on the inner or outer surface. Further, there is no reason provided by the references cited or any other reason provided by the Examiner for placing the implant coating on the inner surface of the stent. Additionally, it is known to put a lubricious coating on the outer surface to assist in reducing the friction during insertion into the body lumen (Michal, col 1, lines 17-21). It would be obvious to one of ordinary skill in that art that any lubricious coating in Savin would be on the outer surface of the stent. Thus, Savin fails to disclose an implant coating on the inner surface of the stent as recited in claim 1.

Furthermore, Savin fails to disclose an adhesion resistant treatment on the outer surface of the balloon (accessible surface) that is in physical communication with the inner surface of the stent. The Examiner refers to column 4, lines 55-57, however this passage merely states, "a lubricating solution can be provided between the balloon 14 and sleeve 18 and 20 to aid in release of stent 16 from the sleeves." Thus, Savin does not disclose an adhesion resistant coating that is located between the implant and the delivery device, but rather provides that a "lubricating solution" may be between the balloon and the sleeves. The sleeves 18 and 20 are not part of the stent 16, and Savin does not state that there is any coating between the stent and the balloon, or even between the stent and the sleeves. Thus, Savin fails to disclose an adhesion resistant treatment as recited in claim 1.

Furthermore, claim 1 recites that "the implant adhesion-resistant treatment prevents the implant coating from being stripped from an implant surface." Since Savin fails to describe a coating on the inner surface of a stent, there would be no motivation to provide an adhesion resistant coating on the delivery device to preserve a non-existent coating on the inner surface of the stent. Thus, Savin does not disclose all the limitations of claim 1 (and all claims that depend therefrom).

Furthermore, with respect to claims 28-30, in addition to the above arguments, Savin also does not disclose any therapeutic in the lubricating solution or anywhere on the balloon or the stent.

It is noted that the Examiner has added claims 24-32 to this rejection but does discuss any of the limitations of these claims. The Examiner is requested to provide support for this rejection or withdraw the rejection.

Regarding Michal, as discussed above, Savin does not disclose all the limitations of claim 1, and Michal does not cure the deficiencies. Michal describes a therapeutic or lubricious coating for an intracorporeal medical device that allegedly strongly adheres to the surface of the device. The embodiments of Michal describes *either* a stent or a catheter having a coating, but nowhere are these two embodiments combined together, and there is no motivation for such a combination. As such, Michal does not disclose an implant coating on the inner surface of the stent that interfaces with the delivery device or an adhesion resistant treatment on the outer surface of the delivery device that is in physical communication with the implant.

For example, Michal describes and illustrates a first embodiment of a catheter 11 having a balloon 13 with a coating 18 on the outer surface (See Figure 1 and col. 6, lines 34-42). In a different embodiment, Michal describes and illustrates a stent on a catheter. In this embodiment, only the stent 30 is described and illustrated as having a coating 18 (See Figures 8 and 10-12 and col. 12, lines 8-23). Thus, when a stent and a catheter are described in combination, Michal specifically does not disclose a coating on both the stent and a coating on the catheter. This supports Applicants' position that Michal is only directed to a lubricious, therapeutic coating on any single intracorporeal medical device (whether a stent or a catheter) and does not disclose any relationship between coatings on two different interfacing medical devices—which is what the present claims are directed to. Thus, Michal does not disclose an adhesion resistant treatment on the surface of the delivery device that interfaces with the implant. The Examiner cannot simply pick and choose between embodiments of a reference and combine them if there is no motivation or suggestion to do so. Furthermore, if Michal intended to have a coating on both the stent and the catheter, it would be shown in the embodiment of Figure 8 and 10-12. Thus, the lack of such a disclosure teaches away from this combination.

Although it may be known to use a lubricious coating on a catheter for ease of insertion into a body lumen, as described by Michal, there is no disclosure or teaching of a catheter having an outer surface coated when this surface is covered by a stent. In fact, if a stent were placed on a catheter for insertion, a lubricious coating on the outer surface of the catheter for ease of insertion into the body lumen would be superfluous, since the catheter would be covered by the stent. The outer surface of the stent may have a lubricious or therapeutic coating, but there would be no motivation to also coat the outer surface of the catheter, since it would no longer be in contact with the body lumen.

The Examiner states that the motivation for combining Michal and Savin is "in order to deliver therapeutic and pharmaceutical agents to a targeted area to inhibit or prevent restenosis." Although this may provide motivation for providing a therapeutic on the outer surface of the stent that interfaces with the body lumen, this would still not provide motivation for providing an implant coating on the inner surface of the stent that interfaces with the delivery balloon. Additionally, neither Savin or Michal disclose an adhesion resistant treatment on the outer surface of the delivery device that is in physical communication with the implant.

The present invention coats the area of the catheter that is in contact the stent in order to prevent stripping the stent coating when the stent is removed from the catheter and implanted in the body lumen. Such a problem was not even contemplated by Michal. Michal is directed to a wholly distinct issue of creating a lubricious or therapeutic coating that allegedly strongly adheres to the device. Thus, the combination of Michal and Savin does not disclose all of the limitations of claim 1 (and all claims that depend therefrom).

With regard to the second grounds of rejection, for the reasons discussed above, Michal and Savin do not disclose all of the limitations of claim 1, and all claims that depend therefrom, and Wang does not cure these deficiencies. Wang describes a balloon catheter that has a portion with a lubricity gradient. However, the catheter is lubricious to allow movement within the lumen of the body, not to allow for release of a removable implant placed on the outer surface. In fact, Wang does not disclose any such removable implant, let alone an implant with a coating, wherein the adhesion resistant treatment prevents the coating from being stripped from the implant. Thus, the combination of Michal, Savin, and Wang does not disclose all the limitations of claim 1, and all claims which depend therefrom.

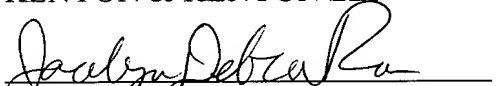
Conclusion

In view of the foregoing, the Examiner erred in finally rejecting claims 1, 3, 5-14 and 24-32. Accordingly, favorable action on this Pre-Appeal Brief Request for Review is respectfully requested.

Any fees for extension(s) of time or additional fees required in connection with the filing of this response, are hereby petitioned under 37 C.F.R. § 1.136(a), and the Commissioner is authorized to charge any such required fees or to credit any overpayment to Kenyon & Kenyon's Deposit Account No. 11-0600.

Respectfully submitted,
KENYON & KENYON LLP

Dated: January 28, 2008



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